

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/502,328 Confirmation No. 3294
Applicant : ZIMMERMAN *et al.*
Filing or § 371 date : 19 MAY 2005
TC/A.U. : 1648
Examiner : M. MOSHER
Docket No. : CS-118
Customer No. : 62,479

§ 1.132 DECLARATION

Sir:

I, Daniel H. ZIMMERMAN, PhD, hereby declare as follows:

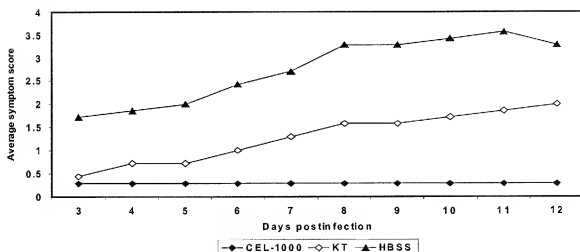
1. I am one of the inventors of the captioned application and am familiar with the subject matter of the captioned application and with the Office Action mailed on April 3, 2008.

2. The AR86 foot pad viral encephalitis model. The following studies using the claimed polypeptides were performed to prevent or treat a viral encephalitic infection with S.A.AR86, which is an alpha virus model for arbovirus encephalitides. The normal disease progression following footpad challenge of mice with AR86 includes paresis/paralysis, aggressive behavior, tremors, and death similar to HSV-1. A/J mice (21 day old) were treated with the claimed polypeptides or control peptide three days prior to challenge. The results are shown in Fig. 1.

3. Initial disease signs were observed in the control and peptide treated mice on the third day but no signs were observed for the claimed polypeptides treated animals. Whereas 6 of

7 untreated, S.A.AR 86 challenged animals exhibited severe neurological signs, none of the 7 the claimed polypeptides treated mice showed signs of neurological problem and only one mouse showed very mild evidence of infection; thereby indicating that the claimed polypeptides can prevent RNA as well as DNA virus infections and block the disease progression of two very different viruses.

Fig. 1

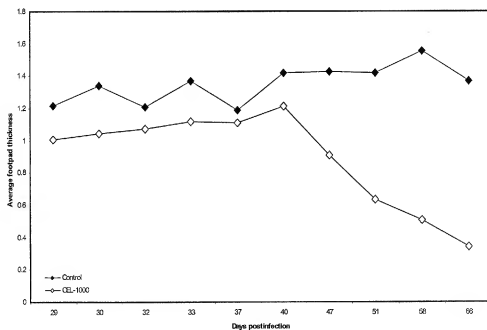


4. Studies with *Leishmania*. The following studies using the claimed polypeptides were performed to prevent or treat a parasitic infection with *Leishmania* *sps*. As a model for parasitic diseases, a strain of *L. major* was selected. Mice (A/J) were treated with the claimed polypeptides (100µg/ mouse) 14 days before challenge with promastigotes. Control groups

received only HBSS emulsified with 50 μ L ISA 51. The animals were monitored for signs of disease in terms of swelling of the footpad starting at 3 weeks post infection for over 9 weeks. Mouse feet from the claimed polypeptides treated animals had the same thickness as uninfected, untreated feet whereas the feet from the untreated animals were swollen indicating the presence of parasite infection and inflammation.

5. As shown in Fig. 2, the claimed polypeptides prevented disease.

Fig. 2

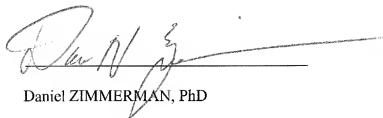


Declarant Daniel H. ZIMMERMAN sayeth:

I declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true and further, that any false statements so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code., and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

07/02/08

Date

A handwritten signature in dark ink, appearing to read 'Dan N. Zimmerman', is written over a horizontal line. The signature is stylized with a large 'D' and a long horizontal stroke extending to the right.

Daniel ZIMMERMAN, PhD